Case 1:19-md-02875-RMB-SAK Document 1244-16 Filed 05/14/21 Page 1 of 4 PageID: 28490

EXHIBIT M

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY CAMDEN VICINAGE

Document 1244-16

PageID: 28491

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION

MDL No. 2875

Honorable Robert B. Kugler, District Court Judge

Honorable Thomas I. Vanaskie (Ret.), Magistrate Judge

DECLARATION OF LINHONG (LINDA) LIN

- 1. My name is Linhong (Linda) Lin.
- 2. I am the Director of Regulatory Affairs of Zhejiang Huahai Pharmaceutical Co., Ltd. ("ZHP").
- 3. I have been the Director of Regulatory Affairs at ZHP since November 2016. Prior to my current position, I was the Director of Regulatory Affairs for ZHP's API division.
 - My deposition in this matter is scheduled for May 3-6, 2021(U.S. time). 4.
- 5. I submit this declaration to clarify the very limited role that ZHP's Chairman, Baohua Chen, plays in ZHP's interactions with the U.S. Food and Drug Administration ("FDA").
- 6. Although FDA communications are sometimes addressed to Mr. Chen in his role as the head of ZHP, I, as well as my team members in the Regulatory Affairs Department, are responsible for coordinating all communications with the FDA. Mr. Chen is not involved in drafting or compiling such communications.
- 7. In addition, I have been present at every FDA inspection of ZHP's facilities since 2004.

PageID: 28492

- 8. During all of the inspections for which I was present, I served as the primary FDA liaison for ZHP.
- 9. Generally speaking, during FDA inspections, Mr. Chen may participate in the welcome meeting and final meeting with the FDA. However, during the vast majority of the inspection, he is not present. Rather, as previously noted, I serve as ZHP's liaison with the FDA during such visits.
- 10. In addition, my department along with the Quality Assurance Department identify subject matter experts who will communicate with the FDA about specific aspects of manufacturing, such as testing, quality, equipment maintenance, etc., during the inspection. The subject matter experts are expected to provide substantive responses to FDA regarding questions their area of expertise. Mr. Chen is never identified as such a subject matter expert, and thus during the inspection does not provide the type of substantive responses expected of the subject matter experts.
- 11. Although Mr. Chen is listed as the "most responsible person" in some FDA reports, this is not a reflection of his role with respect to FDA communications, but instead is a reflection of the fact that within ZHP's corporate hierarchy, he was the highest level person present at ZHP's facilities at the time of the FDA inspection that is the subject of the report.

Case 1:19-md-02875-RMB-SAK Document 1244-16 Filed 05/14/21 Page 4 of 4 PageID: 28493

I DECLARE UNDER PENALTY OF PERJURY UNDER THE LAWS OF THE UNITED STATES THAT TO THE BEST OF MY KNOWLEDGE THE FOREGOING IS TRUE AND CORRECT.

Executed on April 30, 2021 in Linhai, Zhejiang 317024, China.

Linhong (Linda) Lin, Declarant